GE Healthcare

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Certified Mail Return Receipt Requested

URGENT RECALL NOTICE

PLEASE TAKE ACTION TO INFORM ALL USERS OF THE RELEVENT SYSTEM (S) OF THESE ISSUES AND HOW TO ADDRESS THEM

February 28, 2007

To: **Director/Manager of Radiology**

Subject: **Product Safety Issues**

Affected Products: **OEC® 9800, OEC® FluoroTrak 9800 Plus, OEC® 9800 Plus, OEC® 9800MD Motorized C-arm System, OEC® 9900 Elite, OEC®, 9900 EliteMD Motorized C-arm System, OEC® 9900 EliteNAV, OEC® 8800 C-arm System**

Our records indicate that your facility has one or more of the following GEHC OEC products:

- OEC® 9800
- OEC® FluoroTrak 9800 Plus
- OEC® 9800 Plus
- OEC® 9800MD Motorized C-arm System
- OEC® 9900 Elite
- OEC® 9900 Elite*MD* Motorized C-arm System
- OEC® 9900 EliteNAV
- OEC® 8800 System

GE Healthcare Surgery has identified two (2) potential safety issues with the systems listed above that have had either the x ray tube and/or the collimator replaced.

GEHC Surgery has identified two issues with the systems listed above that have had either the x ray tube and/or the collimator replaced. **If your facility is receiving this notification our records indicate that your OEC® 9800, OEC® FluoroTrak 9800 Plus, OEC® 9800 Plus, OEC® 9800MD Motorized C-arm System, OEC® 9900 Elite, OEC® 9900 EliteMD Motorized C-arm System, OEC® 9900 EliteNAV, OEC® 8800, System may be affected by one or both of these issues.**

The possible improper replacement of either the collimator or x ray tube may have resulted in a compromising of the beam limiting provisions on your system, therefore a potential exists for less effective

stray radiation control measures which could result in additional unwanted x-ray exposure to the user and patient.

The system may be non compliant with CFR 21 Sec. 1020.32 with respect to the beam limiting, maximum entrance AKR (air kerma rate) requirements and leakage radiation provisions if one of the following situation exists:

- The primary collimator is missing and the system has not been properly calibrated
- The secondary collimator ring is missing and a collimator calibration has not been performed.

Internal testing by GEHC Surgery has determined that the standard service practices in place would most likely eliminate the occurrence of the two situations listed above. As a result, any non-compliance to CFR 21 Sec. 1020.32 is unlikely and the product may continue to be used.

Solution:

GEHC Surgery is working on inspecting potentially affected systems and repaired them as appropriate as soon as possible at no charge to your facility. GEHC Surgery will be contacting your facility in the immediate future to schedule the inspection of your system.

If you have any questions or concerns regarding these issues, please do not hesitate to contact the service team for further information at 800-874-7378 option 8. Information is available at this number 24 hours per day, 7 days a week.

Thank you,

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